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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,562	06/17/2005	Kristopher Buchanan	09138.0070	2677

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WASHINGTON, DC 20001-4413

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,562	Applicant(s) BUCHANAN ET AL.	
	Examiner NATHAN A. BOWERS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75,90-113,116-118,120 and 121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75,90-113,116-118,120 and 121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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1) Claims 75 and 90-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Custance (US 6238910) in view of Reichler (US 5578270).

With respect to claim 75, Custance discloses an automated sample processing system for processing a plurality of samples each on a respective carrier according to a processing protocol. Specifically, Custance indicates that samples are positioned on slides, which are in turn placed within individual carrier retention devices in the form of slide plate assemblies (Figure 1:106). This is disclosed in column 62 lines 55-67. Column 3, lines 26-40 teach that active temperature regulation elements including thermal management modules (Figure 1:104) are also provided to monitor the temperature of each sample slide during processing. Figure 1 and column 7, lines 18-67 indicate that each slide is positioned just above various heating elements and temperature sensors. Because column 2, lines 55-67 specifically teach that each of the thermal management modules are operate independently, it is understood that each slide may be inserted or removed during the processing protocol without interrupting a processing of another sample. Column 3, lines 1-25 additionally discloses the use of a plurality of removable reagent containers (Figure 1:118) arranged in a first plurality of holding locations (i.e. drawers) in a reagent section. The reagent containers are in proximity to first (Figure 1:112) and second (Figure 1:116) carrier sections that each contain a plurality of slide plate assemblies located in holding locations (i.e. drawers). Custance, however, does not expressly state that the two carrier sections are physically separated by the reagent section.

At the time of the invention, it would have been obvious to position the reagent section disclosed by Custance between the first and second carrier sections. This proposed reconfiguration merely represents a simple rearrangement of parts that would require only slight structural alterations, and would not change the functionality or mode of operation of the device at all. See MPEP 2144.04.

Custance still differs from Applicant's claimed invention because Custance does not expressly indicate that a moveable robotic member is used to dispense fluid on the plurality of carriers.

Reichler discloses an automated system for processing a biological sample using a plurality of work stations. Reichler teaches in column 5, line 52 to column 6, line 20, column 8, lines 43-50, column 16, lines 26-63, column 18, lines 57-63 and column 20, lines 39-50 that samples are moved between various work stations using a robotic arm (Figure 3:190) in communication with a pipette and pressurization means.

Custance and Reichler are analogous art because they are from the same field of endeavor regarding biochemical sample processing stations.

At the time of the invention, it would have been obvious to provide the Custance system with a moveable robotic member capable of dispensing fluid to each carrier. One of ordinary skill would have recognized that the fluid dispensing robotic arm of Reichler could either replace the manifold fluid delivery system of Custance, or, in the alternative, could be used in combination with the existing manifold fluid delivery system of Custance. As evidenced by Reichler, robotic arms for handling reagents and liquid

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samples are well known in the art, and capable of being implemented in an efficient and predictable manner.

With respect to claims 90-95, Custance and Reichler disclose the system in claim 75 wherein the processing system is capable of executing a variety of different techniques. Column 1, lines 12-25 and column 2, lines 1-28 of Custance further state that the system can operate as either an automated immunohistochemistry processing system or a fluorescent in-situ hybridization processing system. The apparatus is further designed to accommodate DNA probe and/or antibody based staining procedures.

With respect to claims 96-98, Custance and Reichler disclose the system in claim 95 wherein an active temperature reduction element is additionally provided. In column 7, lines 18-67, Custance teaches that cooling of the slide is accomplished through the use of Peltier coolers.

With respect to claims 99-101, Custance and Reichler disclose the system in claim 95 wherein the active temperature regulation element comprises a temperature ramp up and ramp down element, thus inducing regulated temperature increases and decreases within the sample. This is described in column 7, lines 63-67 of Custance, and generally throughout the reference.

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2) Claims 102-113, 116-118, 120 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Custance (US 6238910) in view of Reichler (US 5578270) and Ammann (US 20050233370).

With respect to claims 102-108, Custance and Reichler disclose the system set forth in the rejections above. Custance discloses at least one container having a reagent therein, as well as a sample carrier retention device. Sample temperature control elements are provided for regulating the temperature of the contents of the sample carrier retention device. Custance, however, does not expressly disclose that reagent temperature control elements are provided for regulating the temperature of reagents before they are applied to the sample.

Ammann discloses an automated system for processing a plurality of reaction receptacles each capable of holding and transporting a sample. Reaction receptacles are transported to an arrangement of incubators (Figure 4:600,602,604,606) where they are maintained at a predetermined temperature. Paragraphs [0130], [0332] and [0337]-[0369] state that reagents are stored in separate containers located within a reagent cooling bay (Figures 35-39). Ammann teaches that thermoelectric modules and fan units provide the desired cooling capacity, and are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers.

Custance and Ammann are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to equip Custance's reagent storage containers with cooling elements and a control system capable of

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regulating the temperature within the reagent storage containers. Reagents typical of microarray processing systems are known in the art to be temperature sensitive and susceptible to degradation if maintained under undesirable conditions. As evidenced by Ammann, it is well known in the art to keep reagents at cool temperatures during storage to ensure that they do not prematurely expire.

With respect to claims 109-113, Custance, Reichler and Ammann disclose the apparatus set forth in claim 102 as set forth in the 35 U.S.C. 103 rejections above. In addition, Custance clearly indicates that a sample temperature control element is provided to ramp up and ramp down the temperature of the sample maintained within the carousel retention device during processing. This has been described in the rejections above.

With respect to claims 116 and 117, Custance, Reichler and Ammann disclose the apparatus set forth in claim 102 as set forth in the 35 U.S.C. 103 rejections above. Custance additionally describes the use of a rinse buffer in column 3, lines 1-25. Ammann also discloses rinsing and washing steps throughout the reference. As described above, Ammann further teaches that thermoelectric modules and fan units are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers.

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With respect to claims 118, 120 and 121, Custance, Reichler and Ammann disclose the apparatus set forth in the 35 U.S.C. 103 rejections above. As previously noted with regard to Custance, it is understood that since each slide is independently and removably mounted over a different thermal management module, each slide may be inserted or removed during the processing protocol without interrupting a processing of another sample.

3) Claims 75 and 90-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Custance (US 6238910) in view of Reichler (US 5578270) and Kalra (US 6495106).

Custance and Reichler disclose the system set forth in the rejections above. As described above, it is understood that the Custance apparatus is fully capable of inserting/removing a single slide during processing without interrupting the processing of other samples. However, in order to expedite prosecution, the Kalra reference has been provided as evidence that it is known in the art to insert/remove a sample carrier during processing without interrupting the processing of other samples.

Kalra discloses an automated system in which a dispensing head (Figure 4:70) is used to add various reagents to a plurality of sample slides (Figure 1:190) according to a predetermined protocol. Column 17, lines 54-61 state that slides can be removed from the system without interrupting the processing of remaining slides.

Custance and Kalra are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to ensure that the Custance apparatus is capable of inserting or removing a single slide without interfering with the processing of other slides. Kalra teaches in column 17, lines 54-61 that this is beneficial because it allows one to continue slide processing continuously with a minimum of intervention by the user. One of ordinary skill would have recognized that different slides may require different processing protocols (see Custance column 2, lines 55-67), and that it would therefore be desirable to remove a first treated slide while a second slide is still being processed.

4) Claims 102-113, 116-118, 120 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Custance (US 6238910) in view of Reichler (US 5578270) , Ammann (US 20050233370) and Kalra (US 6495106).

Custance, Reichler and Ammann disclose the combination set forth in the rejections above. As described above, it is understood that the Custance apparatus is fully capable of inserting/removing a single slide during processing without interrupting the processing of other samples. However, in order to expedite prosecution, the Kalra reference has been provided as evidence that it is known in the art to insert/remove a sample carrier during processing without interrupting the processing of other samples.

Kalra discloses an automated system in which a dispensing head (Figure 4:70) is used to add various reagents to a plurality of sample slides (Figure 1:190) according to a predetermined protocol. Column 17, lines 54-61 state that slides can be removed from the system without interrupting the processing of remaining slides.

Custance and Kalra are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to ensure that the Custance apparatus is capable of inserting or removing a single slide without interfering with the processing of other slides. Kalra teaches in column 17, lines 54-61 that this is beneficial because it allows one to continue slide processing continuously with a minimum of intervention by the user. One of ordinary skill would have recognized that different slides may require different processing protocols (see Custance column 2, lines 55-67), and that it would therefore be desirable to remove a first treated slide while a second slide is still being processed.

Response to Arguments

Applicant's arguments filed 04 January 2010 with respect to the 35 U.S.C. 102 rejections involving Custance have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Custance with Reichler.

Reichler is relied upon as evidence that the use of robotic members for transporting liquid samples and reagents within a work station is well known in the art. One of ordinary skill would have therefore recognized that the moveable robotic arm of Reichler would either be used in cooperation with the existing fluid delivery system of Custance, or be used to replace the existing fluid delivery system of Custance. One of ordinary skill would have understood that the fluid dispensing systems of Custance and

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Reichler are functionally equivalent, and would have therefore been motivated to implement either liquid handling means.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathan A Bowers/
Examiner, Art Unit 1797